

In re: Kenneth R. Gersing
Serial No.: 09/803,492
Filed: March 9, 2001
Page 14 of 20

REMARKS

Applicant appreciates the thorough examination of the present application that is reflected in the Official Action of August 11, 2005. In order to advance the present application to allowance, the non-elected claims have been officially withdrawn, and Claim 39 has been canceled. However, Applicant respectfully submits that the remaining claims are patentable for the reasons that now will be described.

The Election/Restriction Requirement Will Not Be Traversed

Applicant appreciates the Examiner's consideration of Applicant's remarks regarding the examination of Invention III. In response to the Examiner's indication that Invention II and Invention III have acquired a separate status in the art, Applicants have now withdrawn Claims 1-8, 24-30, 32-34 and 36-38, reserving the right to pursue these claims in a divisional application.

The Drawing Objection Has Been Overcome

The drawings were objected to because reference number 362 has not been described in the specification. In response, Page 17, line 12 has been amended to provide the reference to Block 362. No new matter is introduced. Applicant regrets this inadvertent omission.

The Objection to the Specification Has Been Overcome

The Abstract has been amended so that it does not exceed 150 words in length. Accordingly, the objection to the specification has been overcome.

The Claim Objections Have Been Overcome

The typographical error in Claim 23 has been corrected as noted by the Examiner. Applicant appreciates the Examiner's careful review, which found this typographical error.

Claims 9-23, 31, 35 and 39 Are Statutory Under 35 USC §101

Claims 9-23, 31, 35 and 39 stand rejected under 35 USC §101 because the claimed invention is allegedly directed to non-statutory subject matter. Applicant

In re: Kenneth R. Gersing
Serial No.: 09/803,492
Filed: March 9, 2001
Page 15 of 20

respectfully submits, however, that the claims are statutory under MPEP Section 2106. Moreover, since the time that the Office Action has been mailed, the U.S. Patent and Trademark Office has implemented new "Interim Guidelines for Examination of Patent Applications for Patent Matter Eligibility" (OG Notices 22 November 2005). The claims are clearly statutory under these Interim Guidelines. In particular, independent Claims 9, 31 and 35 are system, method and computer program product analogs of one another. Accordingly, they will not be analyzed separately. Rather, representative Claim 9 will be analyzed.

Claim 9 relates to "[a] psychiatric information system" and is replete with recitations concerning psychiatric patients, assessments, scales, emergency rooms and outpatient visits. A psychiatric information system clearly has utility, accomplishes a practical application, and clearly does not fall within the §101 judicial exceptions of a law of nature, natural phenomena or an abstract idea, under the Interim Guidelines. Rather, psychiatric information systems clearly are practical applications that produce useful, concrete and tangible results under the Interim Guidelines.

As discussed in the Manual of Patent Examining Procedure (MPEP):

The claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601-02. The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research....

[T]he following [example illustrates a] claimed [invention] that [has] a practical application because [it produces] useful, concrete, and tangible result: ...

- "[T]ransformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces 'a useful, concrete and tangible result' -- a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades." *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601....

MPEP, Sec. 2106(II)(A.), page 2100-6, cols. 1-2. (Emphasis added.) As further discussed in the MPEP:

In re: Kenneth R. Gersing
Serial No.: 09/803,492
Filed: March 9, 2001
Page 16 of 20

Office personnel have the burden to establish a *prima facie* case that the claimed invention as a whole is directed to solely an abstract idea or to manipulation of abstract ideas or does not produce a useful result. Only when the claim is devoid of any limitation to a practical application in the technology arts should it be rejected under 35 U.S.C. Sec. 101. ... An applicant may assert more than one practical application, but only one is necessary to satisfy the utility requirement.

MPEP, Sec. 2106(II)(A.), page 2100-7, col. 1. (Emphasis added.)

Applicant respectfully submits that the psychiatric information system of Claim 9 provides a useful, concrete and tangible result. In addition, Applicant submits that Claim 9 is not devoid of any limitation to a practical application in the technology arts as set forth above.

For at least these reasons, Claims 9-23, 31 and 35 clearly recite statutory subject matter. Moreover, in the event that the rejection under 35 USC §101 is maintained, the Examiner is respectfully requested to analyze Claims 9-23, 31 and 35 under the Interim Guidelines that are now in effect.

Independent Claims 9, 31 and 35 Are Patentable Over U.S. Patent 6,067,523 to Bair et al. In View of U.S. Patent 6,757,898 to Ilсен et al.

Independent Claims 9, 31 and 35 stand rejected under 35 USC §103(a) as being unpatentable over Bair et al. in view of Ilсен et al. Assume, for the sake of argument, that all of the Examiner's analysis with respect to Bair et al. at Page 8-9 of the Official Action is correct. However, the Official Action still concedes, at Page 9, that "Bair does not expressly disclose discrete data elements". In particular, Claim 9 recites:

9. (Original) A psychiatric information system comprising:
 - a psychiatric diagnosis dialogue box that is configured to capture psychiatric diagnoses of psychiatric patients, as discrete data elements;
 - a past psychiatric history dialogue box that is configured to capture past psychiatric histories of psychiatric patients, as discrete data elements;
 - a social history dialogue box that is configured to capture social histories of psychiatric patients, as discrete data elements;
 - a mental status exam dialogue box that is configured to capture results of standardized mental status tests of psychiatric patients, as discrete data elements; and

In re: Kenneth R. Gersing
Serial No.: 09/803,492
Filed: March 9, 2001
Page 17 of 20

a database repository that is configured to store the discrete data elements that are captured by the psychiatric diagnosis dialogue box, the past psychiatric history dialogue box, the social history dialogue box and the mental status exam dialogue box. (Emphasis added.)

In an attempt to supply the missing teaching, the Examiner cites Ilsen et al. Column 16, lines 45-52. However, this passage of Ilsen et al. merely states:

The ePPi core architecture achieves both configurability and scalability by combining industry standard non-proprietary components in a unique way that takes into account the thousands of possible relationships that could possibly occur among patients, providers, staff, conditions, discrete data elements and the like, to produce a proprietary architecture that allows for low impact, rapid implementation and flexibility.

This passage simply does not describe or suggest capturing psychiatric diagnoses of psychiatric patients as discrete data elements; capturing past psychiatric histories of psychiatric patients as discrete data elements; capturing social histories of psychiatric patients as discrete data elements; or capturing results of standardized mental status tests of psychiatric patients as discrete data elements, as clearly recited in Claim 9. Accordingly, even if there was some motivation to combine Ilsen et al.'s *Electronic Provider-Patient Interface System* (see the Ilsen et al. title) with Bair et al.'s *System and Method for Reporting Behavioral Health Care Data* (see the Bair et al. title), the above-quoted passage of Ilsen et al. simply would not describe or suggest the above-noted recitations of Claim 9. Stated differently, neither of the references, nor their combination, describes or suggests the use of discrete data elements in psychiatric treatment.

As noted in the "Background of the Invention" section of the present application at Page 1, lines 12-19:

Medical information processing systems, methods and computer program products are widely used in hospitals, clinics, physicians' offices, research studies and/or other medical environments, to capture medical information. The medical information that is captured can be stored in one or more databases, and can be manipulated as database elements.

However, in sharp contrast to other fields of medicine, psychiatry generally is a text-based practice, wherein patient histories, diagnoses, assessments and treatment plans are described using free-form text. (Emphasis added.)

In re: Kenneth R. Gersing
Serial No.: 09/803,492
Filed: March 9, 2001
Page 18 of 20

Moreover, as stated in the present application at Page 2, lines 8-16:

Psychiatry has a rich tradition of clinical information being recorded into a descriptive free-text prose. The nuances of a patient's history and the description of a patient's life may be recorded in the richness of the author's writings. Embodiments of the present invention can facilitate this rich and important aspect of the psychiatry, while simultaneously collecting discrete data elements, like medication side effects, lab values, medical history and/or allergies that psychiatrists may desire to know in order to deliver quality care. In fact, embodiments of the invention can collect discrete data elements on every aspect of a patient's medical record, from social and developmental history to physical exams. (Emphasis added.)

As also noted in the present application at Page 10, lines 5-14:

The discrete data elements that are collected by the emergency room module 110, the outpatient module 120, the scales module 130, the research module 150, and the treatment plan module 170 can offer a unique set of advantages over conventional free text. Data elements can be manipulated, queried and inserted. They can be used for research, to populate forms, for regulatory requirements and/or for utilization review. These are all important aspects of a regulated health care industry, but often are at cross-purposes in delivering efficient, sensitive care to psychiatric patients. Embodiments of the present invention can collect these elements, store them in the database repository 180, and automatically and seamlessly embed them within an electronic record.

Applicant respectfully submits that to establish a *prima facie* case of obviousness, the prior art reference or references when combined must teach or suggest all the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *See* MPEP § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art *also suggests the desirability of the combination*. *See* MPEP §2143.01(citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990)). As emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be *clear and particular*, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re*

In re: Kenneth R. Gersing
Serial No.: 09/803,492
Filed: March 9, 2001
Page 19 of 20

Dembiczak, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). In another decision, the Court of Appeals for the Federal Circuit has stated that, to support combining or modifying references, there must be particular evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

With all due respect, the motivation provided at Page 9 of the Official Action "to discover relationships among the data" is not the type of clear and particular motivation that is required by the MPEP and the case law. Finally, even if the references were somehow combined, they would merely provide "thousands of possible relationships that could possibly occur among patients, providers, staff, conditions, data elements and the like, to produce a proprietary architecture" as noted in the cited passage of *Ilsen et al.* The recitations of Claim 9 simply would not be described or suggested.

For at least these reasons, Claim 9 is patentable over *Bair et al.* in view of *Ilsen et al.* Analogous Claims 31 and 35 are patentable for the same reasons. This analysis will not be repeated for the sake of brevity.

Many of the Dependent Claims Are Separately Patentable

The dependent claims are patentable at least per the patentability of the independent claims from which they depend. Moreover, many of the dependent claims are separately patentable.

For example, dependent Claims 10-17 describe other dialog boxes that are used to capture other data as discrete data elements. The Official Action concedes that the primary reference *Bair et al.* does not describe these discrete data elements. Moreover, the specific recitations of Claims 10-17 are not described or suggested by the passage of *Ilsen et al.* Accordingly, Claims 10-17 are independently patentable.

Moreover, Claims 18-23 recite other modules that are configured to operate from the discrete data elements that are provided in Independent Claim 9. Again, since it would not be obvious to provide the elements of independent Claim 9 as discrete data elements, it certainly would not be obvious to operate on these discrete data elements using the modules of Claims 18-23. The tertiary references, U.S. Patent

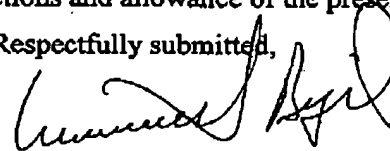
In re: Kenneth R. Gersing
Serial No.: 09/803,492
Filed: March 9, 2001
Page 20 of 20

5,772,585 to Lavin et al., U.S. Publication 2003/0055679 to Soll et al. and U.S. Patent 5,235,702 to Miller, describe various modules in totally different contexts, and do not suggest using the claimed modules to operate on the discrete data elements that are claimed. Accordingly, these claims are also independently patentable.

Conclusion

Applicant again appreciates the thorough examination and the Examiner's pointing out of various errors. These errors have been corrected and many of the claims have been withdrawn or canceled to advance prosecution. However, Applicant has now shown that the pending claims are statutory under 35 USC §101 and are unobvious under 35 USC §103. Accordingly, Applicant respectfully requests withdrawal of all the outstanding rejections and allowance of the present application.

Respectfully submitted,

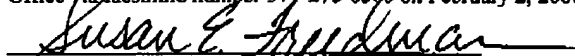


Mitchell S. Bigel
Registration No. 29,614
Attorney for Applicants

Customer Number 20792
Myers Bigel Sibley & Sajovec, P.A.
P.O. Box 37428
Raleigh, NC 27627
919-854-1400
919-854-1401 (Fax)

CERTIFICATION OF FACSIMILE TRANSMISSION UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office via facsimile number 571-273-8300 on February 2, 2006.



Susan E. Freedman

Date of Signature: February 2, 2006